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R&D, Inc., Norton (Waterford) Ltd., and Teva Pharmaceuticals USA, Inc.*

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

TEVA BRANDED
PHARMACEUTICAL PRODUCTS
R&D, INC., NORTON (WATERFORD)
LTD., and TEVA
PHARMACEUTICALS USA, INC.,

Plaintiffs,

v.

AMNEAL PHARMACEUTICALS OF
NEW YORK, LLC, AMNEAL
IRELAND LIMITED, AMNEAL
PHARMACEUTICALS LLC, and
AMNEAL PHARMACEUTICALS INC.,

Defendants.

Civil Action No. 23-cv-20964
(SRC-MAH)

**DECLARATION OF
LIZA M. WALSH**

Electronically Filed

I, Liza M. Walsh, hereby declare as follows:

1. I am an attorney admitted to practice before this Court and a partner

with the law firm Walsh Pizzi O'Reilly Falanga LLP, counsel for Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc., Norton (Waterford) Ltd., and Teva Pharmaceuticals USA, Inc. (collectively, "Plaintiffs"). I am fully familiar with the facts set forth herein.

2. I submit this Declaration in support of Plaintiffs' Opening Claim Construction Brief.

3. Attached as **Exhibit 1** is a true and correct copy of U.S. Patent No. 9,463,289 ("the '289 patent").

4. Attached as **Exhibit 2** is a true and correct copy of U.S. Patent No. 9,808,587 ("the '587 patent").

5. Attached as **Exhibit 3** is a true and correct copy of U.S. Patent No. 10,561,808 ("the '808 patent").

6. Attached as **Exhibit 4** is a true and correct copy of U.S. Patent No. 11,395,889 ("the '889 patent").

7. Attached as **Exhibit 5** is a true and correct copy of ProAir® HFA Label (10/2004), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2004/21457lbl.pdf.

8. Attached as **Exhibit 6** is a true and correct copy of ProAir® HFA Label (Rev. 03/2012), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021457s026lbl.pdf.

9. Attached as **Exhibit 7** is a true and correct copy of FDA Guidance for Industry: Integration of Dose-Counting Mechanisms into MDI Drug Products (2003) (“2003 FDA Guidance”) produced by Defendants in this action.

10. Attached as **Exhibit 8** is a true and correct copy of an excerpt of the file history for U.S. Patent App. No. 14/103,324, March 7, 2016 Response (“Mar. 7, 2016 Resp.”).

11. Attached as **Exhibit 9** is a true and correct copy of an excerpt of Merriam-Webster’s Medical Desk Dictionary (2005).

12. Attached as **Exhibit 10** is a true and correct copy of EP-A-1486227 (“EP ’227”), excerpted from the file history for U.S. Patent App. No. 15/269,249.

13. Attached as **Exhibit 11** is a true and correct copy of an excerpt of the file history for U.S. Patent App. No. 14/103,324, December 11, 2013 Information Disclosure Statement (“Dec. 11, 2013 Information Disclosure Statement”).

14. Attached as **Exhibit 12** is a true and correct copy of WO 2008/119552 (“WO ’552”), excerpted from the file history for U.S. Patent App. No. 15/269,249.

15. Attached as **Exhibit 13** is a true and correct copy of an excerpt of Webster’s Third New International Dictionary of the English Language Unabridged (2002) (“Webster’s Unabridged 2002”).

16. Attached as **Exhibit 14** is a true and correct copy of an excerpt of Merriam-Webster’s Collegiate Dictionary (11th ed. 2007).

I declare that the foregoing statements made by me are true.

Dated: August 14, 2024

/s/ Liza M. Walsh

Liza M. Walsh